



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0590; FRL-9911-54]

Coco alkyl dimethyl amines; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of coco alkyl dimethyl amines (CAS Reg. No. 61788-93-0) when used as an inert ingredient (emulsifier) in pesticide formulations applied to crops preharvest at a concentration not to exceed 0.5% by weight. Technology Sciences Group Inc., 1150 18th St., NW., Suite 1000, Washington, DC 20036, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of coco alkyl dimethyl amines.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0590, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDFNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0590 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0590, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of October 25, 2013 (78 FR 63938) (FRL-9901-96), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10622) by Technology Sciences Group Inc., 1150 18th St., NW., Suite 1000, Washington, DC. 20036. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of coco alkyl dimethyl amines (CAS Reg. No. 61788-93-0) when used as an inert ingredient (emulsifier) in pesticide formulations applied to crops preharvest at a concentration not to exceed 0.5% by weight.

That document referenced a summary of the petition prepared by Technology Sciences Group Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has approved of the use of coco alkyl dimethyl amines at a maximum concentration not to exceed 0.5% by weight in the final end-use formulation. This limitation is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in document Coco Alkyl Dimethyl Amines: CASRN 61788-93-0 Decision Document for the Proposed Use of Coco Alkyl Dimethyl Amines as an Inert Ingredient in Pesticide Formulations Under 40 CFR 180.920 in docket ID number EPA-HQ-OPP-2013-0590.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for coco alkyl dimethyl amines, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with coco alkyl dimethyl amines follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by coco alkyl dimethyl amines as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In 2004, the Agency's High Production Volume (HPV) reviewed 23 fatty nitrogen derived amines. Coco alkyl dimethyl amines was among the group of fatty nitrogen derived amines. In instances where complete data sets were not available, the American Chemistry Council (ACC), as part of the High Production Volume (HPV) Test Challenge Program for Fatty Nitrogen Derivatives, utilized data derived from structurally closely related compounds. The predominant alkyl species in coco alkyl dimethyl amines is the dodecyl (C₁₂) group with the other alkyl species being the tetradecyl (C₁₄), hexadecyl

(C₁₆), and octadecyl (C₁₈) groups. *N,N*-dimethyl-1-dodecanamine (CAS Reg. No. 112-18-5) is a closely related substance in that the chemical structure is similar, the carbon chain length is similar and its physical/chemical properties are similar. *N,N*-dimethyl-1-dodecanamine and other related alkyl dimethyl amines were used in assessing coco alkyl dimethyl amines (CADA).

The coco alkyl dimethyl amines exhibit low toxicity via the acute oral, dermal, and inhalation routes of exposure. In rats the acute oral LD₅₀ is > 1,000 milligrams/kilogram body weight/day (mg/kg bw/day). The acute dermal LD₅₀ is > 3,385 mg/kg bw/day in rabbits. It is corrosive to the skin and irritating to the eyes of rabbits. An acute inhalation study was not available with the coco alkyl dimethyl amines, however, data are available for an acceptable surrogate compound, n-tallow alkyl derivatives of 2,2'-iminobis ethanol (CAS Reg. No. 61791-44-4). The acute inhalation LC₅₀ is > 0.6 milligram/Liter (mg/L) in rats.

A 28-day toxicity study was conducted using Sprague-Dawley rats which received an oral gavage dose of 0, 50, 150, or 300 mg/kg bw/day. At 150 mg/kg bw/day, animals displayed mild adverse behavior, including snout rubbing. A NOAEL of 50 mg/kg bw/day was observed in this study.

There was no evidence of mutagenicity in the Ames test for *N,N*-dimethyl 1-tetradecanamine (CAS Reg. No. 112-75-4), *N,N*-dimethyl 1-hexadecanamine (CAS Reg. No. 112-69-6), and *N,N*-dimethyl 1-octadecanamine (CAS Reg. No. 124-28-7). *N,N*-dimethyl-1-dodecanamine (CAS Reg. No. 112-18-5) was not clastogenic in an *in vivo* mammalian erythrocyte micronucleus test.

A gavage reproductive/developmental toxicity screening study was conducted where *N,N*-dimethyl-1-dodecanamine (CAS Reg. No. 112-18-5) was administered to Sprague-Dawley rats. At 150 mg/kg bw/day, mortality, increased mean implantation loss, decreased mean viability index and abnormal maternal behavior was observed in the dams and reduced weight in pups. The maternal, developmental and reproduction NOAEL was 50 mg/kg bw/day.

None of the amines discussed in the American Chemistry Council High Production Volume challenge document were mutagenic. As noted in the HPV challenge, “The vast majority of the *in vitro* and *in vivo* genotoxicity tests gave no indication of genotoxic potential for primary aliphatic amines” (which includes coco alkyl diethyl amines). The available feeding study for cyclohexylamine and 2-year feeding studies with sec-butylamine and octadecylamine showed no tumorigenic potential.”

In addition, the Agency conducted additional review of coco alkyl dimethyl amines using DEREK software analysis to determine if there were any alerts for carcinogenicity or other chronic toxicity. The results of the DEREK analysis indicated that there were no “ALERTS” for carcinogenicity. Based on the lack of concern regarding mutagenicity and lack of carcinogenicity in animal studies for surrogate chemicals and lack of any carcinogenicity alerts in the DEREK analysis, the EPA concluded that coco alkyl diethyl amines are unlikely to pose a carcinogenic risk.

No dermal toxicity or dermal absorption studies are available for coco alkyl diethyl amines. A dermal absorption study is available for 1-dodecanamine which is structurally closely related. The dermal absorption of 1-dodecanamine was determined to

be 60%. The coco alkyl diethyl amine is a larger molecule than 1-dodecanamine, therefore, it is not expected to be absorbed at a greater rate.

No studies were found specific to the metabolic pathway or toxicokinetic properties of coco alkyl dimethyl amines in mammalian systems. However, based on the knowledge of metabolism of structurally similar compounds in mammals, hepatic dealkylation readily occurs with secondary and tertiary amines, with the methyl groups leaving preferentially. Oxidation of the alpha carbon via cytochrome P450, forms a carbinolamine intermediate that will spontaneously cleave to form a secondary amine and a carbonyl compound. Subsequent, dealkylation of the secondary amine will take place at a slower rate. In a more minor pathway, hydroxylation of the nitrogen atom by hepatic oxidases may take place. Fatty acids are primarily excreted as CO₂.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of

exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

No acute endpoint of concern was identified in the available database, therefore *N,N*-dimethyl-1-dodecanamine is not expected to pose an acute hazard. The chronic reference dose was based on data from co-critical studies, a 28-day oral toxicity study and a reproduction and developmental screening study on *N,N*-dimethyldodecylamine (CAS Reg. No. 112-18-5). In the 28-day repeat dose feeding study in rats, all animals showed rubbing of the snouts in the bedding material between test days 2 and 28, immediately after dosing for a duration of approximately 5 minutes. In a reproduction and developmental screening studies in rats, mortality, increased mean implantation loss, decreased mean viability index, reduced pup weight and abnormal maternal behavior were observed at 150 mg/kg bw/day. The NOAEL was 50 mg/kg bw/day in both studies. The uncertainty factor of 1,000X was used for chronic dietary assessment (10X for intra-individual variability, 10X for interspecies extrapolation and 10X Food Quality Protection Act Safety Factor (FQPA SF). No appropriate dermal or inhalation toxicity studies are available for the exposure assessment. However, the FQPA SF of 10X is retained due to the lack of guideline long-term study(ies) and lack of a 28-day inhalation toxicity study. Dermal absorption was assumed to be 60% and inhalation absorption is assumed to be 100% oral equivalent. The acceptable MOEs for dermal and inhalation exposure are 1,000.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to coco alkyl dimethyl amines, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from coco alkyl dimethyl amines in food as follows:

Because an acute endpoint of concern was not identified, an acute dietary exposure assessment is not necessary. In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM-FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The Inert Dietary Exposure Evaluation Model (I-DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the

Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for coco alkyl dimethyl amines, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Based upon the requested use pattern coco alkyl diethyl amines as an emulsifier that aids in the spray application of pesticides, EPA does not expect non-occupational (i.e., residential) pesticide handler exposures. However, if it is used in pesticide formulations in residential setting then it could result in short- and intermediate-term residential exposure and EPA has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to coco alkyl diethyl amines. It is possible that non-dietary exposure (primarily dermal) could occur as a result of non-pesticidal uses of coco alkyl dimethyl amines such as use in detergents, fabric softeners or anti-static agents. The dietary assessment indicates 3.8% of the RfD for the total U.S. population and 14.1% for children 1-2 years of age (the population most at risk). In light of the highly conservative dietary exposure assessment, the relatively low amount of projected dietary exposure compared to the

RfD, and the primary route for non-dietary exposure (dermal), the EPA believes exposure from non-dietary sources will not exceed the Agency's level of concern. In addition, the combined dermal and inhalation MOEs from possible pesticidal residential uses are in the range of 13,000 to 1,666,000.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found coco alkyl dimethyl amines to share a common mechanism of toxicity with any other substances, and coco alkyl dimethyl amines does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that coco alkyl dimethyl amines does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. *Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is

commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In a reproductive toxicity/developmental screening study in rats, neither qualitative nor quantitative fetal susceptibility was observed. Maternal toxicity (mortality and abnormal maternal behavior), developmental and reproduction toxicity (increased implantation loss, decreased mean viability index, reduced pup weight) effects were observed at the same dose, 150 mg/kg bw/day. The NOAEL was 50 mg/kg/day.

3. *Conclusion.* EPA has determined that it lacks reliable data to apply an additional safety for the protection of infants and children lower than 10X. The decision is based on the following findings:

i. The toxicity database for coco alkyl diethyl amines is incomplete.
The following acceptable studies are available: 28-day Oral toxicity study in rats
Reproduction/Developmental Screening study in rats.

EPA has retained a FQPA factor of 10X due to lack of a long term study conducted evaluating all current guideline parameters, the limited number of animals used in the reproductive/developmental study and the lack of an inhalation toxicity study.

ii. Neurotoxicity and immunotoxicity studies were not available for review.

However, evidence of neurotoxicity or immunotoxicity was not observed in the submitted studies. Therefore, an immunotoxicity study or a developmental neurotoxicity study is not required at this time.

iii. There is no evidence that coco alkyl dimethyl amines results in increased susceptibility in *in utero* rats. In a reproductive toxicity/developmental screening study in rats, neither qualitative nor quantitative fetal susceptibility was observed.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to coco alkyl diethyl amines in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by coco alkyl dimethyl amines.

Given the relatively low toxicity demonstrated by coco alkyl dimethyl amines and the very conservative exposure assessment used, EPA has determined that, despite the incompleteness of the toxicity database, an additional SF of 10X will be protective of infants and children.

E. Aggregate Risks and Determination of Safety Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated

by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, coco alkyl diethyl amines is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to coco alkyl dimethyl amines from food and water will utilize 14.1% of the cPAD for children 1-2 years of age, the population group receiving the greatest exposure. There are no residential uses for coco alkyl dimethyl amines. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of coco alkyl diethyl amines is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The quantitative short-term aggregate risk assessment is not necessary because the total dietary exposure for the U.S. population is 3.8% of the cPAD, and any possible short-term residential exposure from handler use would not be a significant contributor to overall risk nor exceed levels of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The quantitative intermediate-term aggregate risk assessment is not necessary because the total dietary exposure for the U.S.

population is 3.8% of the cPAD, the Agency believes any possible intermediate-term residential exposure from handler use would not be a significant contributor to overall risk nor exceed levels of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity, coco alkyl dimethyl amines is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to coco alkyl dimethyl amines residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of coco alkyl dimethyl amines in or on any food commodities. EPA is establishing a limitation on the amount of coco alkyl dimethyl amines that may be used in pesticide formulations. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution that contains greater than 0.5% of coco alkyl dimethyl amines in the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for coco alkyl dimethyl amines.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for coco alkyl diethyl amines (CAS Reg. No. 61788-93-0) when used as an inert ingredient (emulsifier) in pesticide formulations applied pre-harvest to growing crops at a maximum not to exceed 0.5% by weight in the final pesticide formulation.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain

any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 3, 2014.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, the table is amended by alphabetically adding the following inert ingredient after the entry for “Cis-isomer ***” to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
*	* * *	* *
Coco alkyl dimethyl amines (CAS Reg. No. 61788-93-0)	Not to exceed 0.5 % in pesticide formulation.	Emulsifier
*	* * *	* *